

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Fred Wehling et al.	Art Unit: 1618
Serial No.:	10/743,118	Examiner: Samala
Filed:	December 22, 2003	Confirmation No.: 7497
Title:	THERAPEUTIC EFFERVESCENT COMPOSITION	

MAIL STOP APPEAL BRIEF-PATENTS

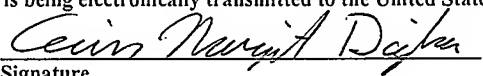
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REPLY BRIEF

Appellants submit the following Reply Brief in response to the Examiner's
Answer dated November 30, 2007.

CERTIFICATE OF TRANSMISSION

I hereby certify under 37 CFR §1.8(a) that this correspondence is being electronically transmitted to the United States Patent and Trademark Office, by EFS-Web, on January 29, 2008.


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I. Supplemental Argument Addressing Statements in the Examiner's Answer

As a preliminary matter, Appellants wish to note, that after repeated readings of the Examiner's Answer, Appellants still do not understand the manner in which the references are being combined to arrive at the tablet of claims 1-26, the composition of claims 29 and 30, the mouthwash of claim 31 or the methods of claims 32-36. Appellants submit that they are entitled to be placed on notice as to the rationale supporting the outstanding rejection and the manner in which the references are being combined to arrive at the claimed inventions. It seems axiomatic that this notice must be set forth in a manner that is coherent and readily understandable to the skilled artisan. See, e.g., *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ____ (2007) quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (Rejections based on obviousness grounds must be supported with some articulated reasoning coupled with a rational underpinning). If "the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the Examiner to explain why the combination of the teachings is proper." See, MPEP 2143 citing *Ex parte Skinner*, 2 U.S.P.Q.2d 1788 (Bd. Pat. App. & Int. 1986). Here no such analysis or explanation has been set forth. Accordingly, Appellants again submit that a *prima facie* case of obviousness of the pending claims has not been established. For this reason alone, the rejection of claims 1, 3 and 5-36 under 35 U.S.C. 103 over Gioffre et al. in view of Schobel or Rockliffe et al. or Andersen cannot stand, and Appellants respectfully request that the Board overrule the same.

Claim 1

The Examiner's Answer appears to take the position that claim 1 is anticipated by the "cited reference," although the Examiner's Answer does not identify the reference to which he is referring, Appellants assume it is Gioffre et al (see, Examiner's Answer, page 4, second full paragraph). Appellants first note that there is no rejection outstanding of claim 1 under 35 U.S.C. § 102(b) over any reference, let alone Gioffre et al. Assuming that this is a new ground of rejection, Appellants now address this rejection.

Claim 1 requires, in relevant part for purposes of this discussion, that the tablet dissolve in water having a temperature of at least 38°C to form a clear solution. The Examiner appears to take the position that the chewable tablets of Gioffre et al. would

inherently dissolve in water to form a clear solution. This is not true. The majority of the disclosure of Gioffre et al. is directed to dentifrice compositions in the form of extrudable, shape-retaining dental creams (see, Gioffre et al., e.g., col. 5, lines 54-59). Gioffre et al. disclose that their dentifrice compositions, which would include their chewable tablet, include an inorganic oxide material such as aluminosilicate (Gioffre et al., col. 2, lines 17-21). Inorganic oxide materials are not inherently water soluble. Aluminosilicate is not water soluble. Therefore, it is not the case that the chewable tablet version of Gioffre et al.'s dentifrice composition would inherently dissolve in water to form a clear solution, as required by claim 1. Therefore, Gioffre et al. cannot anticipate the tablet of claim 1.

The Examiner's Answer then asserts that claim 21 of Gioffre et al. anticipates or renders obvious the tablet of claim 1. Appellants wish to note that a careful reading of claim 21 of Gioffre et al. reveals that it does not teach or suggest including more than one flavoring agent in the chewable tablet of Gioffre et al. Claim 21 of Gioffre et al. depends from claim 1, which recites, in relevant part, "an extrudable tubed dessiccated [*sic*] dental cream formulation of from about 1 to about 99 percent by weight inorganic oxide material." (Emphasis added.) Claim 1 of Gioffre et al. does not recite a tablet or a flavoring agent. Claim 21 of Gioffre et al. recites, in relevant part, "said dentifrice contains at least one addition component selected from the group consisting of...flavoring agents." Thus, notwithstanding the assertions to the contrary in the Examiner's Answer, claim 21 does not teach or suggest including two flavoring agents in a tablet. Rather, claim 21 discloses that one flavoring agent could be selected for inclusion in an extrudable dental cream that is in a tube. For at least these additional reasons, the rejection of claim 1 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel et al. or Rockliffe et al. or Andersen cannot stand, and Appellants respectfully request that it be overruled by the Board.

The Examiner next appears to take the position that since the Schobel composition dissolves in water to yield a clear effervescent solution, the dentifrice of Gioffre et al. inherently dissolves in water to yield an effervescent solution. As a preliminary matter, Gioffre et al. do not teach or suggest that their extrudable dentifrice cream yields an effervescent solution when contacted with water. Gioffre et al. also do

not teach or suggest that their compositions dissolve. Moreover, nothing in the record establishes that dentifrice compositions that are extrudable and shape-retaining inherently dissolve in water to form a clear solution (see, Gioffre et al., e.g., col. 5, lines 54-59). Gioffre et al. further disclose that the inorganic oxide materials in their composition act as an abrasive (*Id.*, col. 3, lines 34-35). The inorganic oxide materials of Gioffre et al. could not act as an abrasive if they were in solution. Therefore the dentifrice compositions of Gioffre et al. do not inherently dissolve in water to form a clear solution.

The question of whether or not the Schobel formulation dissolves in water to form a clear solution is also a red herring. The formula of the effervescent composition of Schobel is nothing like the formula of the dentifrice composition of Gioffre et al. Therefore, there is no scientific basis on which to base the assumption that the two compositions will exhibit identical properties when placed in water.

The proposed combination of Gioffre et al. and Schobel is further deficient in that nothing in Gioffre et al. or Schobel indicates that combining the effervescent composition of Schobel with the dentifrice cream of Gioffre et al. will somehow result in a composition that dissolves in water to form a clear solution. To render a claim obvious based upon a proposed combination of references, there must be a reason to make such a combination. The compositions of Schobel are dissolved in water and swallowed to enable the oral administration of a therapeutic agent, i.e., the compositions of Schobel are delivered to the stomach. The compositions of Gioffre et al., in contrast, must stay in the mouth if they are to serve their intended purpose, i.e., cleaning teeth. Swallowing the dentifrice composition of Gioffre et al. would defeat Gioffre et al.'s purpose, i.e., to clean teeth. Gioffre et al. do not teach or suggest that their dentifrice compositions are swallowed. In addition, nothing in the record establishes that dentifrice compositions are inherently swallowed. Therefore, the skilled artisan familiar with Gioffre et al. would have no reason to look to Schobel and further would find Schobel to provide no reason to modify the dentifrice composition of Gioffre et al.

The proposed combination of Gioffre et al. and Schobel is further deficient in that it would not result in the tablet of claim 1. For the proposed combination of Gioffre et al. and Schobel to render obvious the tablet of claim 1, the resulting composition must dissolve in water having a temperature of at least 38°C to form a clear solution. As

demonstrated above, the Gioffre et al. composition must include an inorganic oxide material, which is water insoluble. Schobel does not teach or suggest omitting the inorganic oxide material from the Gioffre et al. composition. Therefore the skilled artisan would have no reason to do so. Accordingly, the proposed combination of Gioffre et al. and Schobel could not result in a tablet that dissolves in water having a temperature of at least 38°C to form a clear solution. For at least these additional reasons, the rejection of claim 1 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel cannot stand, and Appellants respectfully request that it be overruled by the Board.

Claims 3 and 5-36 are further distinguishable under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockcliffe et al. or Andersen for at least the reasons set forth above in distinguishing claim 1.

Claims 8, 9, 23 and 24

With respect to claims 8, 9, 23 and 24, the Examiner takes the position that it is Appellant's burden to demonstrate unexpected results as to the tablet hardness set forth in claims 8, 9, 23 and 24. This is an incorrect statement of the law. The Patent Office bears the initial burden of establishing a *prima facie* case of obviousness. The burden does not shift to Appellant to rebut the *prima facie* case by, for example, demonstrating unexpected results unless and until the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is first satisfied by the Patent Office. *See, In re Piasecki*, 745 F.2d 1468, 223 U.S.P.Q. 785 (Fed. Cir. 1984). Here, the Examiner has not discharged his initial burden. In order to establish a *prima facie* case of obviousness of claim 8, the Examiner must first establish that the prior art teaches a range of tablet hardness that encompasses or touches on the hardness range claimed in claim 8. *See, In re Woodruff*, 919 F.2d 1575, 1578, 16 U.S.P.Q.2D (BNA) 1934, 1936 (Fed. Cir. 1990). This he has not done. Here, neither one of the cited prior art references, i.e., Schobel and Gioffre et al., teaches a tablet hardness that encompasses or touches the range set forth in claim 8. Gioffre et al. also do not teach or suggest that tablet hardness is important to their chewable tablet. Moreover, nothing in the cited art teaches or suggests that a tablet having a hardness of at least 10 kilopounds would be suitable for the chewable tablet required by Gioffre et al. Therefore, Gioffre et al. provide no reason or motivation to the

skilled artisan to modify the chewable tablet of Gioffre et al. so as to produce a tablet having a hardness of at least 15 kilopounds, as required by claim 8.

Schobel does not cure the deficiencies of Gioffre et al. Schobel does not teach or suggest that tablet hardness is important to his tablet. The only mention of tablet hardness in Schobel occurs in Example 1 wherein Schobel describes tableting the specific composition of his Example 1 to a tablet hardness of from 7-9 strong cobb units, which equates to from 5 kp to approximately 6.4 kp. The proposed combination of Gioffre et al. and Schobel thus fails to teach or suggest a tablet having a hardness of at least 15 kp as required by claim 8. Accordingly, a *prima facie* case of obviousness of claim 8 has not been established, and the burden has not shifted to Appellants to rebut the same. For at least these additional reasons, the rejection of claim 8 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel cannot stand and Appellants respectfully request that it be overruled by the Board.

Claims 9, 23 and 24 are distinguishable under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel for at least the same reasons set forth above in distinguishing claim 8.

Claims 21, 22, 25 and 26

With respect to claims 21, 22, 25 and 26, the Examiner takes the position that it is Appellant's burden to demonstrate unexpected results as to the tablet hardness required by claims 21, 22, 25 and 26. This is an incorrect statement of the law. The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. The burden does not shift to Appellant to demonstrate unexpected results unless the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is first satisfied by the examiner. *See, In re Piasecki*, 745 F.2d 1468, 223 U.S.P.Q. 785 (Fed. Cir. 1984). Here, the Examiner has not discharged his initial burden. In order to establish a *prima facie* case of obviousness of claim 21, the Examiner must first establish that the prior art teaches a range of tablet hardness that encompasses or touches on the hardness range claimed in claim 21. *See, In re Woodruff*, 919 F.2d 1575, 1578, 16 U.S.P.Q.2D (BNA) 1934, 1936 (Fed. Cir. 1990). This he has not done. Here, the cited prior art, i.e., Schobel and Gioffre et al., does not teach a tablet hardness the encompasses or touches the range claimed. Gioffre et al. do not teach or suggest that tablet hardness is important

to his chewable tablet. Moreover, nothing in the cited references teaches or suggests that a tablet having a hardness of at least 10 kilopounds would be suitable for the chewable tablet required by Gioffre et al. Therefore, Gioffre et al. provide no reason motivation for producing a tablet having a hardness of at least 10 kilopounds as required by claim 21.

Schobel does not cure the deficiencies of Gioffre et al. Schobel does not teach or suggest that tablet hardness is important to his tablet. The only mention of tablet hardness in Schobel occurs in Example 1 thereof wherein Schobel describes tableting the specific composition of example 1 to a tablet hardness of from 7-9 strong cobb units, which equates to from 5 kp to approximately 6.4 kp. Thus, the proposed combination does not teach or suggest a tablet having a hardness of at least 10 kp as required by claim 21. Accordingly, a *prima facie* case of obviousness of claim 21 has not been established, and the burden has not shifted to Appellants to rebut the same. For at least these additional reasons, the rejection of claim 8 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel cannot stand and Appellants respectfully request that the Board overrule the same.

Claims 22, 25 and 26 are distinguishable under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel for at least the same reasons set forth above in distinguishing claim 21.

Claims 33, 35, and 36

The Examiner's Answer is notably devoid of any discussion regarding the alleged obviousness of claims 33, 35 and 36, which are directed to a method that requires inhaling vapors emitted by a solution. As established in Appellants' Appeal Brief, there is no evidence of record establishing that it was known or obvious to dissolve a tablet of the formula set forth in claim 1 in water to form a clear solution and then to inhale vapors emitted by the solution. There is also no evidence of record establishing that it was known or obvious to dissolve a tablet of the formula set forth in claim 1 in either water having a temperature of 38°C, or boiling water, to form a clear solution and then to inhale vapors emitted by the solution. A *prima facie* case of obvious of claims 33, 35 and 36 thus has not been made. Accordingly, the burden to rebut the same has not shifted to Appellants. Appellants submit, therefore, that the rejection of claims 33, 35 and 36 under

35 U.S.C. § 103 over *Gioffre et al.* in view of *Schobel* cannot stand and respectfully request that the Board overrule the same.

Claim 34

Although the meaning of the statements in the Examiner's Answer is not entirely clear to Appellants, Appellants divine from the same that it is the Examiner's position that Andersen teaches that effervescent tablets that provide a clear solution are uniquely desirable for use as a mouthwash (see Examiner's Answer, page 6). Andersen includes no such teaching. It is noteworthy that the Examiner's Answer contains no citation establishing support for such an assertion.

Andersen also does not suggest dissolving his tablet to form a clear solution and gargling with such a solution, as required by claim 34. Nowhere in Andersen is there a mention of gargling. Andersen does not, for example, teach or suggest that it is necessary to gargle with his tablet composition. Moreover, Andersen's description of the manner in which his tablet is used does not teach or suggest that one could or should gargle with his tablet. Andersen discloses that his tablet can dissolve through the action of the saliva in the mouth (Andersen, col. 3, lines 5-7). Andersen also discloses that a small quantity of water could be added to the mouth of the user (*Id.*, col. 3, lines 6-7). Andersen does not teach or suggest gargling with his tablet or how to do so. Nothing in the record establishes anything to the contrary.

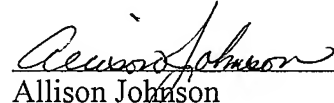
It also appears that the Examiner takes the position that one of ordinary skill in the art would have been motivated to utilize the tablet of *Schobel* as a mouthwash (see, Examiner's Answer, page 6). *Schobel* does not teach or suggest that his tablet is a mouthwash. None of the formulations of *Schobel* include the germicidal agents or the breath fresheners of Andersen. In addition, nothing in Andersen teaches or suggests utilizing the tablet of *Schobel* as a mouthwash. Therefore the skilled artisan would have no reason to employ the tablet of *Schobel* as a mouthwash. Thus, for at least these additional reasons, the rejection of claim 34 under 35 U.S.C. § 103 over *Gioffre et al.* in view of *Schobel* or Andersen is unwarranted and Appellants respectfully request that the Board overrule the same.

The claims now pending in the application are in condition for allowance and such action is respectfully requested. Appellants request that the Board overrule the rejections of Record with directions to pass the above-captioned application to issue.

Please charge any fees or credit any over payments to Deposit Account No. 501,171.

Respectfully submitted,

Date: January 29, 2007


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